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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,772	02/12/2004	Atsuo F. Fukunaga	10437-69	2944

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/777,772

Applicant(s)

FUKUNAGA ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
4a) Of the above claim(s) 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/23/06; 12/28/05</u> | 6) <input checked="" type="checkbox"/> Other: <u>IDS 8/26/04</u> |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species:

Species I, as seen in Fig. 7A, is directed towards a unilimb circuit having an inner and outer conduits that are both pleated.

Species II, as seen in Fig. 13A, is directed towards a unilimb circuit having an inner conduit that is pleated and an outer conduit with a fixed length.

The species are independent or distinct because the operability for species I is different from species II.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

2. During a telephone conversation with Dan Schein on 9/26/06 a provisional election was made without traverse to prosecute the invention of Species I, claims 1-29. Affirmation of this election must be made by applicant in replying to this Office action. Claim 30 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 8/24/06, 12/28/05 and 5/23/06 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 11-14 recite the limitations "said first tube", "said second tube" and "said outer tube". There are insufficient antecedent basis for these limitations in the claims.

8. Claim 15 recites the limitation "the pleats" and "said first pleated". There are insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3, 15, 17 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,463,755 to Suzuki.

(claim 1) Suzuki teaches a multilumen, unilimb breathing circuit comprising first 2 and second 5 conduits, each of the conduits having a proximal and a distal end (see Fig. 1), wherein the proximal end of the first conduit can be operatively connected to an inlet for respiratory gases via port 17, and the second conduit can be can be operatively connected to an outlet for respiratory gases via port 6, wherein the first and second conduits comprise pleated or corrugated tubing (col. 5, lines 26-39); and wherein the first and second conduits meet the flow requirements for spontaneous or assisted ventilation.

(claims 2 and 3) The first and second conduits have a common proximal fitting (Fig. 6) and a common distal fitting (Fig. 4).

(claim 15) Fig. 1 shows the first and second conduit comprising pleats or corrugation having wavelengths that are proportional in size.

(claim 17) The first conduit is contained within the second conduit, see Fig. 1.

(claims 26-28) Suzuki teaches an anesthesia system (col. 1, line 14).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. **Claims 4-14, 16, 18-20 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of WO 85/05277 to Clawson et al.**

(claim 4) Suzuki teaches the first and second conduits formed from corrugated tubing (col. 5, lines 26-39) but is silent with regards to the conduits being able to retain its shape after axial extension or contraction, wherein the first conduit will expand or contract in length with corresponding axial expansion or contraction of the second conduit.

However, Clawson teaches a multilumen, unilimb breathing circuit comprising a first **108** and second **110** conduits; wherein the conduits are formed from pleated or corrugated tubing that is capable of retaining its shape (page 5, first complete paragraph); and wherein the first and second conduits have common proximal and distal ends (Fig. 4) so that when the second conduit is expanded or contracted, the first conduit will simultaneously expand and contract along with the second conduit.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Suzuki to use the corrugated tubing of Clawson because using Clawson's corrugated tubing eliminates the need of stocking and shipping breathing circuits of different lengths (page 3, second paragraph). Clawson's corrugated tubing can be increased or decreased to a desired length without cutting or substitution.

(claims 5-7) Suzuki teaches the first and second conduits having a common proximal fitting (Fig. 6) and a common distal fitting (Fig. 4). Therefore, the modified breathing circuit of Suzuki/Clawson will also have a first and second conduits sharing a common proximal fitting and a common distal fitting.

(claims 8-10) It would be inherent that axially extending or contracting the modified breathing circuit of Suzuki/Clawson would also adjust the volume within the first or second conduit; i.e., a shorter tubing would have less volume than a longer tubing.

(claims 11-14) Clawson teaches the first or inner conduit made of the corrugated tubing that can retain its shape. Therefore, the modified first conduit of Suzuki/Clawson

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could have a longer length than the second conduit when the first conduit is not constrained by the mutual fittings since the first conduit could be extended to a retained length and the second conduit could be contracted to a shorter, retained length.

(claim 16) The combination of Suzuki/Clawson discloses the claimed invention except for the conduits having a resistance to flow of less than about 6 cm H₂O at flow rates of up to about 60 l/min. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at the recited ranges, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, it would be obvious to arrive at the recited ranges since Suzuki teaches a device used for providing breathable gases to a patient.

(claims 18-20) Suzuki teaches the first conduit contained within the second conduit and being coaxial therewith (Fig. 1).

(claim 29) Suzuki teaches an anesthesia system (col. 1, line 14).

14. Claims 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of US 5,778,872 to Fukunaga et al.

Suzuki teaches all the limitations of the claims but is silent with regards to the proximal fitting having at least two lumens with filters. However, Fukunaga teaches a similar unilimb breathing circuit having a proximal fitting with two lumens having filters (**158,168**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the proximal fitting of Suzuki to include the

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two filters taught by Fukunaga because it prevent other components connected proximally of the filter from contamination by patient expiratory gases.

15. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki in view of Clawson et al. and in further view of US 5,778,872 to Fukunaga et al.

The above combination of Suzuki/Clawson teaches all the limitations of the claims but is silent with regards to the proximal fitting having at least two lumens with filters. However, Fukunaga teaches a similar unilimb breathing circuit having a proximal fitting with two lumens having filters (**158,168**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the proximal fitting of Suzuki/Clawson to include the two filters taught by Fukunaga because it prevent other components connected proximally of the filter from contamination by patient expiratory gases.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Darwin P. Erez
Examiner
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